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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,689	03/07/2001	Penny Towne	98,541-K	5052

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
1743	8

DATE MAILED: 05/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

mk-8

Office Action Summary

Application No.	Applicant(s)	
09/800,689	TOWNE ET AL.	
Examiner	Art Unit	
Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received. (PCT/US99/20353)
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a)-(d), under 35 U.S.C. 119(e) and under 35 U.S.C. 120 as follows: The instant application does not name at least one common inventor with PCT/US99/20353, and therefore, priority to this application under 35 USC 119(a)-(d) cannot be claimed. The instant application also does not name at least one common inventor with provisional application no. 60/099,018, and therefore, priority to this provisional application under 35 USC 119(e) cannot be claimed. The instant application also does not name at least one common inventor with application serial nos. 09/721,096 and 09/259,240, and therefore, priority to these applications under 35 USC 120 cannot be claimed. The instant application is not a proper continuation of application serial no. 09/259,240, and is not a proper continuation-in-part of application serial no. 09/721,096. Therefore, US Patent no. 6,296,809 to Richards et al, which corresponds to application serial no. 09/259,240, qualifies as applicable prior art under 35 USC 102(e). See MPEP sections 201.07 and 201.08.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The title of the invention in the declaration is different than the title of the invention on the first page of the specification.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means"

Art Unit: 1743

and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprise". Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: Throughout the specification, patent application serial numbers 09/259,240 and 08/995,052 are mentioned. Applicants are requested to provide the corresponding patent numbers for these applications, which are now both patents, i.e. application serial no. 09/259,240 is now US Patent no. 6,296,809, and application serial no. 08/995,052 is now US Patent no. 6,045,759. On page 2 of the specification in the section titled "Reference to Related Applications", it is unclear how the instant application is supposedly related to some of the applications recited in this paragraph. In particular, it is not clear if this application is supposed to be a continuation of application serial no. 09/259,240, and a continuation of International Application No. PCT/US99/04181, in addition to being a continuation-in-part of application serial no. 09/721,096. It is noted that PCT/US99/04181 is not included in the declaration under any of the priority headings. It is also noted that application serial no. 09/721,096 is a 371 of PCT/US99/20353, which in turn claims the benefit of provisional application 60/099,018. Applicants are requested to clarify the relationships among the cited applications and the instant application (i.e. how the instant application is related to all of the applications listed on page 2 of the specification), especially in light of the fact that the instant application does not share any common inventors with any of the cited applications on page 2 of the specification. See paragraph no. 1 above.

Appropriate correction is required.

6. Claims 6-7, 10-12 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite since it is not clear what units of concentration the phrase "10% ethylene glycol" refers to. In other words, is the ethylene glycol present in the composition at a concentration of 10% by volume or 10% by weight? See this same problem in claim 7 with the phrase "5% ethylene glycol", in claim 10 with the phrase "10% SDS", in claim 11 with the phrase "0.3% SDS", in claim 12 with the phrases "5% ethylene glycol" and "0.3% SDS", in claim 17 with the phrases "the concentration of the glycol is less than or equal to approximately 10%" and "the concentration of the SDS is less than or equal to approximately 10%", in claim 19 with the phrases "the concentration of ethylene glycol is approximately 5%" and "the concentration of SDS is approximately 0.3%", and in claim 20 with the phrases "approximately 5% ethylene glycol" and "approximately 0.3% SDS".

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1743

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being obvious over Richards et al (US Patent no. 6,296,809) in view of Hartman et al.

Richards et al teach of a method and apparatus for automatically performing pathological staining and treating of tissue samples. Richards et al teach that it is important to treat the tissue samples analyzed therein so as to improve the accessibility of a stain to target molecules in cells (i.e. proteins, nucleic acids, lipids, etc.). Lack of accessibility is caused by the crosslinking of molecules and antigens in cells due to the fixation and preservation of the cells with aldehydes and other fixatives. Cross-linking of antigens causes a loss of antigenicity due to chemical modifications of antigenic proteins. Richards et al disclose that in order to improve the accessibility of a stain to a molecular target in a cell, the cells of a fixed tissue sample should undergo "cell conditioning". This is done by treating the cells with a composition which comprises a citrate buffer as well as sodium dodecyl sulfate (SDS) and ethylene glycol. See

Art Unit: 1743

lines 54-67 in column 15 and lines 1-16 in column 16 of Richards et al. The conditioning composition has a known molarity, pH and composition. It is noted that Richards et al is considered proper prior art against the instant claims since the effective filing date of the Richards et al patent is before the effective filing date of the instant application, and the instant application does not claim priority to the Richards et al patent. Richards et al fail to teach that the cell conditioning composition contains sodium metabisulfite therein.

Hartman et al teach of a tissue fixative composition that contains therein a bisulfite salt. The bisulfite salt can be a metabisulfite such as sodium metabisulfite. Hartman et al teach that this composition containing sodium metabisulfite serves to improve the morphology, antigen retention and antigenicity of tissue samples. See lines 15-40 in column 2 of Hartman et al.

Based upon a combination of Richards et al and Hartman et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to add sodium metabisulfite to the cell conditioning composition taught by Richards et al since Hartman et al easily determined and adjusted depending upon the user's particular preferences and the objective sought. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller et al*, 105 USPQ 233.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Faustino et al, Rybski et al and Miller et al who teach of compositions therein that contain one or more of citrate buffer, sodium metabisulfite, and polyethylene glycol.

Art Unit: 1743

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on alternate Thursdays and every Monday and Tuesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

April 30, 2002

maureen m. wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700